REMARKS

This Amendment is responsive to the Office Action having a mailing date of April 3, 2007.

Claims 3-25 and 27 have been amended. Claims 32-36 have been added. No new matter has been inserted. Claims 3-28 and 30 and 32-36 remain pending in the application. Applicant respectfully requests reconsideration of the Examiner's rejections.

The Title has been shortened. The specification has been amended to address the Examiner's objections to the priority claims and alleged new matter. The specification has also been amended to include reference numerals 502 and 500 originally shown in Figure 4 but not mentioned in the specification. Figure 5 has been amended to delete reference numeral 15. A replacement sheet for Figure 5 is enclosed herewith.

The Edwards claim rejections.

Applicant incorporates by reference its previous arguments regarding Edwards. Applicant appreciates the Examiner's recognition that Edwards does provide a spirometer which provides audible and verbal instructions. However, Applicant respectfully notes that the audible/verbal instructions provided by Edwards are for the limited purpose of using the Edwards spirometer. It is readily apparent that Edwards fails to teach the claimed device of Applicant.

Edwards is a highly mechanically complicated medical device which requires physical adjustments be made to the device for proper use. The Edwards device is a multi-function modular device encompassing more than one breathing procedure which requires unthreading/threading and unscrewing/screwing in different components of the device, such as, but not limited to, the mouthpiece using a mouthpiece-to-neck attachment means. Col 4, lines 51-54. Furthermore, Edwards also requires configuring the rotor blade in relationship to sensitivity to one of two options depending on whether the user is performing an exhaling or inhaling procedure with the device. Col. 9, lines 13-39. Additionally, Edwards also indicates that the spirometer needs to be frequently calibrated and recalibrated by the patient or user to finely

adjust how easily the rotor rotates in response to given air flow. Col. 10, lines 39-42. The fine and complicated details of how the Edwards spirometer is calibrated are then discussed in the same paragraph. For example, it is indicated that calibration can be performed with a bearing screw (phillipshead or otherwise) that is moved slightly up or down as desired to tighten or loosen the spindle and adjust the sensitivity of the rotor with respect to any given airflow. Col. 10, lines 42-47. Sensitivity is defined as "of such a nature to be easily effective". Thus, in another words, the Edwards sensitivity easily affects his apparatus if not performed correctly by the patient.

Edwards also requires the user to access the calibration screw through an opening beneath the spirometer where a screwdriver can pass. Col. 10, lines 47-49.

Furthermore, Edwards also uses a filter sack which changes color to visually indicate to the user that the mouthpiece and sack combination have already used and thus, to remove the used mouthpiece and replace it with a new one. Col. 5, lines 2-12.

Additionally, Edwards also discusses the modularity of the his device, including the attachment and detachment of several modular sections such as, the rotor section, upper filtration section, lower filtration section, detection and electronics section and air outlet section to and from one another. Col. 8, lines 20-25.

These necessary procedures to ensure that the Edwards device is working properly and are not trivial actions and require that the user of the Edwards device be at least able to see, and apparently is also knowledgeable in the exact assembly and adjustment procedures in order for the patient to use the Edwards device. Being that this is unlikely, Edwards device would then require that live ancillary medical assistance be present for performing these procedures and is a particularly significant problem if the user is blind should assistance be unavailable.

Edwards does disclose providing an alleged voice system containing prerecorded instructions to walk the user through the use of the Edwards spirometer, which should apparently also include the ability to walk the user through the process of calibration of the device itself. Thus, thereby obviating the need for a technician (ancillary medical assistance) to provide such instructions and allowing the Edwards spirometer to be employed as a personal use device. Col

11, lines 13-17. Thus, Edwards teaches that no technician is intended to be present, making it clear that the Edward's device is limited to sighted users who must respond to the complex calibration techniques that the Edwards device instructs, as well as having accessibility to the proper calibration tools, in view of the above description procedures, attachments, sensitivity of rotor blades, detachments and calibrations that must be performed by the user on the Edwards device. Therefore, given these way beyond simple required procedures that must be performed by the sighted user, Applicant respectfully questions, whether a typical sighted user is qualified or can be trusted to correctly perform these procedures that a qualified medical technician should perform on the Edwards device.

Furthermore, the standards of the American Medical Association ("AMA") relating to patient use of personal use devices indicate that calibration must be of a type that is convenient, easily obtainable and usable. As stated above, Edward's device is one that a blind person in particular could not use, due to the complexity of the calibration. Additionally, in a hospital environment, where a sighted patient is seriously ill, it is doubtful that a patient could be asked to perform these required procedures on the Edwards device. Thus, it is also doubtful that the Edwards device satisfies the AMA requirements, even when used by a sighted user, since the calibration requirements are so complex, in consideration of the AMA standards of being convenient and easily usable. Furthermore, it is doubtful that a user comes to the hospital having a screwdriver for calibration purposes, yet alone the correct size screwdriver. Thus, the complexity of calibration for the Edward's device is more complex than a normal personal use device and requires a greater calibration process than those calibration requirements required by the AMA. It is difficult to imagine how one could expect a blind, or even a sighted patient, to use the personal use device Edwards teaches due to the detailed adjustments Edwards requires.

Applicant claims, as amended, indicate that the user of Applicant's medical device can be sighted or blind. Thus, given the physical demands for properly using the Edwards device, it is readily seen that such device could not be used, in particularly by a blind user due to the complexity of calibration, unless a live ancillary medical assistance were present to perform the adjustments required by Edwards.

Edwards is a complex multiple, all inclusive breathing apparatus with complex requirements for usage that are far beyond the normal capability of the sighted or the blind patient, due to these complex procedures for use and would not be possible to be used without a live ancillary medical assistant. As a multiple purpose breathing apparatus requiring different breathing test to be performed at different times, it would be evident that medical assistance would be needed to inform the blind, as well as the sighted user, of which of the various tests to be performed, as well as which time to perform such needed breathing medical test. Thus, the specific structural nature of the Edwards device prevents it from being considered the type of "a medical apparatus" as claimed by Applicant.

As now claimed Applicant's invention permits a sighted or blind user to use the medical apparatus without the presence of ancillary medical assistance to perform any normal ancillary task. Given that Applicant's claims specifically indicate that the medical device can be used by both blind and sighted users, Applicant's comments removing Edwards as a proper medical apparatus should not be considered unduly narrow and are in fact in concert with the broadest interpretation of the claims. Furthermore, claims 3 and 17 do in fact now claim that live human ancillary medical assistance is not given to the sighted or blind user for purposes of prompting initial use of the medical apparatus or informing, instructing or guiding the sighted or blind user, in connection with their use of the medical apparatuses. Claim 3 also now claims that the medical device conventionally required live human medical ancillary assistance, which should be interpreted to mean in the past such medical apparatus would have needed live human assistance. The claims now also state that this previously live human assistance is replaced through the components of the claimed invention.

Edwards also does not prompt a user to initiate use or begin using the spirometer. By this Amendment, the claims have been amended to change the language "prompt use of said medical apparatus" to "prompt the user to initiate use of said medical apparatus". This revision in the claim language now more clearly shows that Applicant's claimed invention on its own, automatically begins prompting the user to use the medical apparatus as needed. Edwards only provides certain verbal instructions on how to use the medical apparatus after the user or other

individual, on his or her own, has activated, calibrated or recalibrated the medical apparatus. Edwards does not prompt the user to calibrate or recalibrate the medical apparatus or to activate or initiate use of the medical apparatus. It is well known to one skilled in the medical field that compliance with utilization by the patient is the most important process for beginning patient recovery.

Accordingly, Applicant respectfully submits that Edwards fails to disclose Applicant's claimed invention. As such, Applicant respectfully requests that the rejection of claims 1-5, 9-11, 14-15 and 17 in view of Edwards be withdrawn.

The Wessel claim rejections.

Wessel only teaches providing rewards through a visual display, without any predetermined voice guidance taught being part of the Wessel device itself. The use of visual displays is continuously discussed throughout Wessel. For example, the Wessel controller includes a first display 30 to display video-game graphics, charts, tables or other information. Col. 2, lines 61-62 and Col. 4, lines 52-54. A second display, separate from the first display, for displaying medical information is provided on a medical diagnostic cartridge. Col. 2, lines 64-66 and Col. 5, lines 7-8. Display 30 is also required to display to the user the reward codes, games, prizes and other non-medical incentives. Col. 5, lines 34-36. Data retrieved is shown on display 60 of cartridge 50. Col. 13, lines 40-42. The above are only a handful of examples of the use of visual displays in the Wessel patent. Given this reliance on visual displays by Wessel, it is clear that the Wessel device cannot be used by the blind or the sighted user without having live ancillary medical assistance, especially given the requirements for knowledge or familiarity of the complexity of aforementioned display equipment, thus requiring guidance for operation. Also, the sighted user may not be familiar with the operation of a GAMEBOY or how to get text messages from a cell phone or the other various embodiments discussed in Wessel, which would thus require live ancillary medical assistance to teach the user in such operations.

Furthermore, Wessel's glucose reader cartridge is inserted into a handheld video-game controller and the visual rewards provided can be associated with playing the video-game. Col. 4,

lines 50-51; Col. 9, lines 63-67. The playing of the video-game and reviewing the visually displayed rewards, shows that Wessel is limited for use by a sighted user and could not be used by a blind person. Wessel's device does not provide self-contained verbal instructions, as claimed by Applicant, for prompting the use to initiate use of the device and for guiding the user during the use of the device. As mentioned above, with respect to Edwards, it is well known to one skilled in the medical field that compliance with use initiation by a patient is the most important process for beginning patient recovery.

The Examiner also relies on the description in Wessel indicating that a "nice job" or other encouragement message is displayed on display 30 of telephone 205. Col 16, lines 28-31.

The Examiner also notes that Wessel states that at a different step the message can include videos, graphics, text, and/or audio to name several examples. Col 16, lines 25-27.

This description in Wessel should not be confusingly interpreted to mean that Wessel is capable of giving audible verbal instructions or prompts, as claimed by Applicant. Wessel is actually silent regarding the device providing audible verbal instructions or prompts. When referring to "audio", Wessel is discussing sound imitations, absent of wordage. Text messages in Wessel are only described and discussed as being visually displayed. Audio is defined as the reproduction of sound and does not means audible verbal instructions to prompt and guide usage, such as a human voice contained within the apparatus as claimed by Applicant. Throughout the Wessel disclosure it is consistently described that the visual display is the predominant form of reward and "audio" is only used for an alarm system to alert the patient.

Furthermore, with the cellular telephone and other embodiments referred to by Wessel, the patient or other user is required to have the ability to adjust or maintain current medical test results or other parameters. Col. 12, lines 37-38. Clearly, under normal conditions, a blind or sighted patient in a hospital is not qualified to adjust his or her own medical test results and such adjusting would be too complex and thus would require ancillary medical assistance.

At column 9 line 33, Wessel teaches that the person utilizing his device is a patient. A patient is defined as "a person under medical care". At column 9. line 64 of Wessel, it is stated that a ""GAME BOY controller is used only to display reward codes, games, prizes, and other

information or incentives that are not directly medically related." Thus, all patients (individuals under medical care) using the Wessel device are expected to comprehend the way to use a GAME BOY, cellular telephone, as well as being expected to know how to send or retrieve messages with these types of devices. It is readily apparent that all patients will not be familiar with GAME BOYS, cellular telephones, and sending or retrieving messages from these devices. Thus, ancillary assistance must be provided to teach the patient (who is obviously sighted in view of the above comments) in the use of these devices. A further problem with Wessel that is avoided and irrelevant with Applicant's claimed invention, is that the operation of a GAME BOY or cellular telephone is not a known teaching per the standards of the AMA requirements for ancillary medical assistants during his or her training. Thus, the ancillary medical assistant may not be able to properly train the patient in the operation of these non-medical devices that Wessel requires.

Accordingly, Wessel cannot be used by (1) every patient without proper ancillary assistance, especially patients who have never used a GAME BOY or cellular telephone, (2) in every hospital setting, especially since electronic devices and cellular telephones may not even be permitted to be operated in the hospital. Again, given the dependence on visual displays Wessel is also limited to sighted users who are previously knowledgeable with the operation of a GAME BOY or cellular telephone or any other non-medical devices required to perform the function of Wessel's invention.

Applicant's claimed system includes conventional medical apparatuses making the claimed invention totally different then the Wessel device. Applicant's claimed system is not dependent on any outside non-medical devices to be used, as taught by Wessel. These outside components required by Wessel, must be used to provide the function of his device, or invention, such that the Wessel video game system and medical cartridge should not be considered a complete medical device by themselves.

Since during use of the Wessel's device visual text messages can come from a remote location, Wessel also discusses encrypting medical testing parameters, which require visual text

messaging. Col. 12, lines 47-50. This again is completely different than Applicant's claimed audible verbal messages.

Wessel also fails to verbally indicate the glucose reading to the user. Wessel only discloses two different visual displays 30 and 60. In certain embodiments, certain messages from a remote location can be transmitted to the Wessel device. Thus, Wessel does not have an audio storage or audio response unit where messages are stored. Wessel provides no audible, verbal instructions, guidance or teachings to a blind or sighted user for using the Wessel device in any of its embodiments (i.e. cellular, GAME BOY, Palm Pilot, etc.). Even the sighted user, especially in a hospital setting, would have difficulty using the Wessel device without ancillary medical assistance.

None of the preferred embodiments of Wessel, contain an audio response unit where audible verbal messages are stored. Nowhere in Wessel, does it provide or store audible, verbal instructions for the sighted or blind in the complexity of using the Wessel device.

Additionally, as the Wessel messages can be sent from a remote location, the Wessel device itself does not decide which message to select from a plurality of stored messages, which to the contrary, Applicant's system being synthesis with medical apparatuses does decide.

Wessel does not teach nor provide any verbal instructions for retrieving any messages required for display per the function of his device. Nor does Wessel in any way make allowances for the blind or even the sighted, in order to show the procedures needed to perform the retrieval as taught for the function of Wessel's devices and retrieval is required as a fundamental portion of the Wessel patent. Wessel does not make allowances for the blind, incapacitated, or the seriously ill, (even diabetics have often have problems seeing), or other diseases. In addition to needing instructions for operating a medical device, the user most likely will also need instructions for using the non-medical equipment necessary to perform retrieval of display techniques taught by Wessel. Thus, the required ancillary medical assistant would also have to be familiar and/or trained in the usage of Wessel's claimed retrieval devices; Palm Pilot, Game Boy, and a variety of other devices including voice or other telephone message retrieval...such as text or MSM messages. Applicant's claimed invention significantly differs from Wessel as it provides

a novel method and system incorporating a self-contained electronic assembly component that requires no patient or ancillary medical assistant to program any features or retrieve any messages. Applicant's claimed invention avoids the complexity of utilizing any device, medical or otherwise, as taught by Wessel, which becomes multiplied immensely, when one is ill, or blind.

With respect to certain claims, Wessel does not disclose a gauge and does not require the user relating to performance a therapeutic or medical procedure using the device. Rather it merely reads a glucose level from a strip inserted into the device/cartridge. Accordingly, the claims discussing a gauge are also not shown by Wessel.

The Wessel patent also does not on its own automatically begin prompting the user to initiate use of the medical apparatus. Applicant's claimed electronic assembly uses a single microcontroller unit to perform all functions. To the contrary, Wessel requires a first processor 95 for processing information regarding the glucose readings and a second processor 130 for controlling the reward to provide the user, which is also a visual reward that the blind would be unable to use.

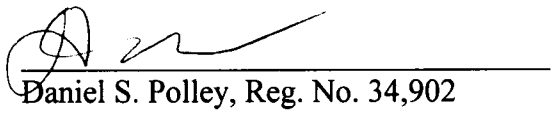
Furthermore, Wessel does not replace ancillary medical assistance, as it describes a live human (doctor, nurse) receiving the glucose score and then based on such score remotely sending a verbal message. Col. 4, lines 8-34; Col. 14, lines 15-22. Applicant's electronic assembly, which includes the audio response unit, is claimed as being self-contained, which is readily seen in the drawings and the associated description of the drawings. Applicant's verbal messages are stored and produced from the electronic assembly without any further remote signal or transmissions. Wessel fails to disclose this claimed feature.

Accordingly, Applicant respectfully submits that the Wessel invention fails to disclose Applicant's claimed invention. As such, Applicant respectfully requests that the rejection of claims 3-28 and 30 in view of Wessel be withdrawn.

In view of the above, Applicant respectfully requests that the Examiner withdraw all Section 102 rejections. Favorable action is respectfully requested. Applicant has completely responded to the Office Action dated August 10, 2006 and Notice dated April 3, 2007.

If there are any additional charges, including extension of time, please bill our Deposit Account No. 503180.

Respectfully submitted,



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